

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

OLIVER SHIH, Individually and on Behalf
of All Others Similarly Situated,

Plaintiff,

v.

AMYLYX PHARMACEUTICALS, INC.,
JOSHUA B. COHEN, JUSTIN B. KLEE,
JAMES M. FRATES, and MARGARET
OLINGER,

Defendants.

Case No. 1:24-cv-00988-AS

**AMENDED CLASS ACTION
COMPLAINT**

JURY TRIAL DEMANDED

TABLE OF CONTENTS

I.	NATURE OF THE ACTION	1
II.	JURISDICTION AND VENUE	4
III.	PARTIES	4
IV.	SUBSTANTIVE ALLEGATIONS	6
A.	Amylyx Markets Cornerstone Drug, Relyvrio, As Offering Unprecedented Hope for Patients Suffering From ALS.....	6
B.	Amylyx Touts The Success Of The Relyvrio Commercial Launch.	9
C.	Amylyx Hid Key Numbers Of New Subscribers And Patient Discontinuations, Artificially Inflating Relyvrio's Commercial Success And Prospects.	12
1.	Amylyx Intentionally Structured Its Launch To Hide Data On New Prescriber Rates And Discontinuations From The Market.	13
2.	Amylyx Misled The Market About Declining New Patient Subscribers Rates And Potential Growth After The Initial Bolus.	14
a.	Mere Months After The Launch, New Patient Subscribers Were Flat After The Initial Bolus Ended.....	14
b.	There Was No Potential For Growth With General Neurologists.	16
c.	The Amylyx Sales Teams Could Not Meet Internal Quotas.	18
d.	Management's Rosy Statements About The Launch's Sales Success Did Not Match The Internal Reality At The Company... ..	19
3.	Defendants' Fraud Is Confirmed By Unethical And Toxic Tactics To Boost New Prescription Numbers After The Initial Bolus.	20
a.	Defendants Try A Desperate, Unethical "Quid Pro Quo" Scheme To Boost Growth.....	21
b.	When Amylyx Failed To Meet Internal Sales Targets After The Bolus, They Played The Blame Game.	22
4.	Unbeknownst To Investors, But Not Defendants, Patients Were Discontinuing Relyvrio Early Into Treatment.	23
5.	By Hiding These Discontinuation Trends, Defendants Overstated The Demand For, And Projections Of, Patient Prescriptions.	24
D.	Materially False and Misleading Statements Issued During the Class Period.....	25
E.	Amylyx's Class Period Filings Did Not Comply With SEC Disclosure Requirements.	44
F.	The Truth Emerges.	47
G.	Post-Class Period Developments.	50
H.	SCIENTER ALLEGATIONS.....	52

I.	PLAINTIFF'S CLASS ACTION ALLEGATIONS.....	55
COUNT I	58	
	(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)	58
COUNT II	61	
	(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)...	61
V.	PRAAYER FOR RELIEF	62
VI.	DEMAND FOR TRIAL BY JURY	63

Lead Plaintiff Oliver Shih (“Plaintiff”), individually and on behalf of all others similarly situated, by Plaintiff’s undersigned attorneys, for Plaintiff’s complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff’s own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff’s attorneys, which included, among other things, a review of the Defendants’ public documents, conference calls and announcements made by Defendants, United States (“U.S.”) Securities and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding Amylyx Pharmaceuticals, Inc. (“Amylyx” or the “Company”), statements from former employees, analysts’ reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial, additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Amylyx securities between November 11, 2022 and November 8, 2023, both dates inclusive (the “Class Period”), seeking to recover damages caused by Defendants’ violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Amylyx is a commercial-stage biotechnology company that engages in the discovery and development of treatments for amyotrophic lateral sclerosis (“ALS”), also known as Lou Gehrig’s disease, and other neurodegenerative diseases. The Company’s products include,

among others, AMX0035 (commercially referred to as “Relyvrio” in the U.S.), a dual UPR-Bax apoptosis inhibitor composed of sodium phenylbutyrate and taurursodiol, for the treatment of ALS in adults in the U.S.

3. Following the U.S. Food and Drug Administration’s (“FDA”) September 2022 approval of Relyvrio for the treatment of ALS in adults in the U.S., Defendants consistently touted the drug’s commercial prospects and prescription rate, offering hope to those suffering from this devastating disease.

4. Yet throughout the Class Period, Defendants made materially false and misleading statements regarding the success of the Relyvrio commercial launch. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) at the time, Defendants knew that the “significant demand” was due to an initial, temporary bolus of patients that, by this time, had stabilized, offering no meaningful opportunity for further growth, (2) at the time, contrary to their representations, Defendants knew the initial bolus was over within months of the launch, (3) and thus, there was no growth potential for newly diagnosed patients with ALS in ALS centers, (4) that there was no opportunity for growth outside the concentrated ALS centers, in the broader neurology community, (5) at the time, Defendants already were aware that high, undisclosed discontinuation rates were occurring, undermining the commercial potential for the launch, (6) those hidden discontinuations inflated the “runway” left for more, new net patient subscribers, and (7) as a result, Defendants’ public statements were materially false and misleading at all relevant times.

5. The truth about the launch’s failure was revealed on November 9, 2023, when Amylyx issued a press release announcing its third quarter (“Q3”) 2023 financial results, including

Q3 GAAP¹ earnings per share (“EPS”) of \$0.30, missing consensus estimates by \$0.12. That same day, on a conference call with investors and analysts to discuss these results, Company management revealed that, despite “a [purported] steady cadence of new prescriptions written in” Q3 for Relyvrio, Amylyx’s “results were impacted by a number of factors” including a “slowdown in net adds” for Relyvrio in Q3, which “was primarily driven by increased discontinuations for a variety of reasons.”

6. That same day, on November 9, 2023, *Investor’s Business Daily* published an article addressing the Company’s disappointing financial results (the “IBD Article”). The *IBD* Article cited an Evercore ISI analyst, who questioned Amylyx’s assertion that the number of new patients starting treatment with Relyvrio was “steady,” noting that his math suggested otherwise and that Amylyx had blocked analysts from viewing Relyvrio’s prescription data in the summer of 2023. The analyst also stated that, “[k]nowing that [Amylyx’s] stock had underperformed in 2023 already, management could have communicated the discontinuations dynamic much earlier,” and that the “[s]tock move today in a bad biotech tape and fund performance doesn’t help investor confidence among folks that have held onto the stock.”

7. Following these disclosures and the publication of the *IBD* Article, Amylyx’s stock price fell \$5.74 per share, or 31.89%, to close at \$12.26 per share on November 9, 2023.

8. Months after this truth about Relyvrio’s launch failure was revealed, the death knell for Relyvrio came when the late-stage clinical trial assessing the drug’s efficacy (the Phoenix trial) failed spectacularly—revealing the drug was no better than a placebo (a sugar pill) in mitigating any symptoms of ALS. In response to this news, Amylyx’s stock dove 82%, and Amylyx withdrew Relyvrio from the market.

¹ “GAAP” refers to the U.S. generally accepted accounting principles.

9. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

II. JURISDICTION AND VENUE

10. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

12. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Amylyx's common stock trades on the Nasdaq Global Select Market ("NASDAQ"), which is located in this Judicial District.

13. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

III. PARTIES

14. Lead Plaintiff, as set forth in the attached Certification, acquired Amylyx securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

15. Defendant Amylyx is a Delaware corporation with principal executive offices located at 43 Thorndike Street, Cambridge, Massachusetts 02141. The Company's common stock trades in an efficient market on the NASDAQ under the ticker symbol "AMLY."

16. Defendant Joshua B. Cohen (“Cohen”) has served as Amylyx’s Co-Chief Executive Officer (“Co-CEO”) at all relevant times. Defendant Cohen is also a Co-Founder of the Company. During the Class Period, Defendant Cohen sold 105,968 shares of Amylyx common stock for total proceeds of over \$3.4 million.

17. Defendant Justin B. Klee (“Klee”) has served as Amylyx’s Co-CEO at all relevant times. Defendant Klee is also a Co-Founder of the Company. During the Class Period, Defendant Klee sold 105,968 shares of Amylyx common stock for total proceeds of over \$3.4 million.

18. Defendant James M. Frates (“Frates”) has served as Amylyx’s Chief Financial Officer at all relevant times. During the Class Period, Defendant Frates sold 100,158 shares of Amylyx common stock for total proceeds of over \$3 million.

19. Defendant Margaret Olinger (“Olinger”) served as Amylyx’s Chief Commercial Officer (“CCO”) at all relevant times. Defendant Olinger left the Company effective December 31, 2023.

20. Defendants Cohen, Klee, Frates, and Olinger are collectively referred to herein as the “Individual Defendants.”

21. The Individual Defendants possessed the power and authority to control the contents of Amylyx’s SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Amylyx’s SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Amylyx, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then

materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

22. Amylyx and the Individual Defendants are collectively referred to herein as “Defendants.”

IV. SUBSTANTIVE ALLEGATIONS

A. Amylyx Markets Cornerstone Drug, Relyvrio, As Offering Unprecedented Hope for Patients Suffering From ALS.

23. Amylyx is a commercial-stage biotechnology company that engages in the discovery and development of treatments for amyotrophic lateral sclerosis (“ALS”), also known as Lou Gehrig’s disease, and other neurodegenerative diseases. Founded in 2013 and based in Cambridge, Massachusetts, the Company’s “main asset” is AMX0035, sold under the commercial name “Relyvrio,” which received FDA approval for the treatment of ALS in September 2022.

24. As Amylyx’s only approved commercial product for sale in the U.S., it is the key product in Amylyx’s commercial pipeline. As one analyst report stated, “Amylyx is a one product company without clear opportunities beyond ALS.” (Bank of America, “New ALS launch addressing huge unmet need; Initiate at Buy, \$50 PO,” Jan. 5, 2023) “While Amylyx has other pipeline assets . . . and can potentially expand to other neurological diseases such as Alzheimer’s and Wolfram Syndrome,” those are in the early stages of development, so “the Company’s near-term focus is on Relyvrio’s commercial execution.” (*Id.*) The success of any such launch thus is critical to Amylyx’s overall success.

25. Amylyx developed Relyvrio to treat ALS, a rare, progressive, and fatal neurodegenerative disease characterized by the degeneration of neurons in the brain and spinal cord. The initial manifestation of the disease ranges from muscle weakness of the limbs to difficulty with speech and swallowing—and over time, patients develop muscle paralysis, inability

to speak or swallow, and respiratory failure leading to certain death in only 2 to 5 years. While all patients develop motor dysfunction, roughly half also develop cognitive or behavioral impairment and 15% develop frontotemporal dementia.

26. About 30,000 people in the U.S., and more than 200,000 worldwide, suffer from this devastating disease. And universally, diagnosis is a shock: more than 90% of people living with ALS have no family history of the disease, and it can strike adults at nearly any age.

27. Even more distressingly—because the current approved drugs to treat ALS at best can extend life mere months—typical treatment is largely focused on supportive care such as symptom management. In addition, the last approved treatment for ALS was issued 25 years before the FDA approved Relyvrio. Given the strong unmet needs in treatment, physicians and patients are often willing to try a new agent either as a monotherapy or as an add-on to existing therapy.

28. Before seeking FDA approval, drugs typically must clear three increasingly challenging clinical-trial hurdles, called “Phases.” Phase I trials are conducted in a small number of volunteers or patients to assess the early tolerability and safety profile, and the pattern of drug absorption, distribution, and metabolism. Next, Phase II trials are conducted in a limited patient population afflicted with a specific disease in order to assess appropriate dosages and dose regimens, expand evidence of the safety profile, and evaluate preliminary efficacy. Finally, Phase III involves larger scale, multicenter, well-controlled clinical trials that are conducted on patients with a specific disease to generate enough data to statistically evaluate the efficacy and safety of the product for approval. Once all are cleared, the company typically submits a “new drug application” to the FDA for commercial assessment.

29. However, given the unmet need in the market, and the fact that patients are desperate for any relief from certain, imminent death, and under pressure from ALS advocacy groups and Congress, the FDA approved Relyvrio for early commercial use despite the fact that Relyvrio was currently in Phase III. In that Phase III trial—which Amylyx dubbed the “Phoenix” study—the Company was conducting “a 48-week, randomized, placebo-controlled, global clinical trial further evaluating the safety and efficacy of [Relyvrio] . . . for the treatment of ALS.”

30. “The primary efficacy outcome” of the trial (i.e., the trial’s main research question) would assess whether, at the end of the 48 weeks, there was any “change from baseline in ALS Functional Rating Scale-Revised (ALSFRS-R) total score.” The ALSFRS-R measures 12 aspects of a patient’s physical function robbed by the disease (everyday functions including speech, salivation, swallowing, handwriting, cutting food, climbing stairs, turning in bed, walking, dressing and hygiene, dyspnea (difficulty breathing), orthopnea (shortness of breath while lying down), and breathing insufficiency), and then each function category is scored from 4 (normal) to 0 (no ability), with a maximum total score of 48 and a minimum total score of 0.² The trial’s “secondary endpoints” (i.e., additional events of interest, but to which the study is not specifically powered to assess) “include quality of life patient-reported outcome assessments, overall survival, and respiratory function.”

31. Given this early FDA approval, and the need to fully assess Relyvrio efficacy long-term, “[b]efore Relyvrio’s approval in September 2022, [Amylyx] executives said they would withdraw the drug [from commercial use] if the late-stage [Phase III Phoenix] data weren’t

² (ALS Pathways, “What is the ALSFRS-R?,” available at, <https://www.alspathways.com/assessingfunction/#:~:text=The%20ALSFRS%20measures%2012,minimum%20total%20score%20of%200>).

positive.” (WSJ, “Wall Street Predicted a Blockbuster, Now the Drug May Be Withdrawn,” March 10, 2024).

32. Leading up to the commercial launch following this FDA approval, Amylyx promised this vulnerable population hope from Relyvrio. Amylyx claimed “our mission is to one day end the suffering caused by” ALS, and since its founding, “[f]rom a dorm room at Brown University in 2013, our Co-CEOs and Co-Founders, Josh Cohen and Justin Klee set out to determine why neurons die, and have ever since been working to develop [Relyvrio], which we believe is the first drug candidate to show function and survival benefits in patients with ALS.” (Amylyx, 10-K, March 13, 2023). “Unlike most other cells in the body that regularly die and are replaced as part of healthy function, mature neurons are normally resistant to cell death and generally cannot regenerate. We believe [Relyvrio] is the first drug candidate to show both a functional and survival benefit in a large-scale clinical trial of patients with ALS.” (*Id.*)

B. Amylyx Touts The Success Of The Relyvrio Commercial Launch.

33. Amylyx commercially launched Relyvrio in the U.S. on October 24, 2022. From the beginning, Defendants touted the strength of that launch in numbers and the potential for growth in new subscriptions. On February 14, 2023, for instance, Defendants filed an 8-K, lauding that “[t]he Company has observed higher demand for RELYVRIO in the U.S. than initially anticipated pre-launch and, as a result, expects to meaningfully exceed fourth quarter and full-year 2022 Wall Street research analyst consensus estimates for revenue.”

34. Indeed, throughout the launch period, Defendants were reporting steady increases in patient subscribers. On March 13, 2023, during the Q&A portion of the Q4/FY 2022 Earnings Call, in response to an analyst question regarding the pace of patients starting treatment with Relyvrio and “a sense for how we think about the pace of starts after” the first quarter (“Q1”) of

2023, Defendant Olinger described this as “seeing an initial bolus in demand” and while they noted “we just don’t know how big this bolus will be or how long it will last,” Defendant Olinger reiterated that “we expect continued growth and interest in demand” and “[w]e really see that we have a lot of runway ahead of us” as far as getting more new subscribers after the bolus. Defendant Klee bolstered that assurance, stating that for this bolus, demand was “very concentrated so far so we have a lot of breadth and depth to continue to look forward to, I think as we expand this product.”

35. These assurances continued on May 11, 2023, when Relyvrio announced it more than “doubled” subscribers from 1,300 to 3,000. Analysts again attempted to get information about how long this bolus would last, and Defendants assured them that demand remained fervent and that there were strong “opportunities for growth” to come. And, on August 10, 2023, for the Q2 2023 earnings call, Defendants announced that number had increased to 3,800, touting “[w]e made strong and steady progress on our commercial launches in [Q2]” with “strong and steady demand in Q2.” Indeed, on that earnings call, Defendant Olinger stated this was just the beginning, as “we have a really large untapped opportunity for growth outside of” the core prescribing group of ALS centers.

36. Yet while touting this seemingly “strong and steady growth” throughout the launch, Defendants refused to provide information about patient discontinuations—a key metric that would impact the purported amount of patients currently on Relyvrio. On November, 10, 2022, the Company released its Q3 financial results. During the Q&A earnings call, Defendant Cohen would not answer directly about “how long [Defendants] expect patients to stay on drugs in [Amylyx’s] model,” stating only that “we haven’t given specific guidance as to time on therapy for our product.”

37. This obfuscation on discontinuation continued well into the launch in 2023. Nearly ten months after the launch, on the August 10, 2023 Q2 earnings call, in response to an analyst question regarding “what are you seeing with respect to . . . discontinuation rates” and whether Defendants “[a]re . . . seeing any emerging trends with respect to the primary reason for discontinuation,” Defendant Olinger said only that “we report on net patients on therapy,” which is “inclusive of any discontinuation” but it is “really too early to see any long-term trends at this point in our launch.”

38. Analysts again pressed about discontinuation rates particularly “among the early patients t[hat] have received [the] commercial drug in 4Q of last year [2022] [who are] presumably some of the[] patients [that] . . . would have been on drug for at least six months now,” and whether Defendants could “provide any color as to what percent of them are still on therapy at this point again just among the patients who started in 4Q.” In response, Defendant Olinger would only say that “again, we’re only going to be reporting on net patient numbers for a quarter” and that “it’s a little too early to really give any trends there.” Defendants Klee and Olinger also dodged yet another question asking for “any color on . . . new prescription trends versus refill trends?” and thus the retention of patients on Relyvrio, to which Defendant Olinger would only state that the Company was “going to continue to work on . . . expansion” of new subscribers with a “number of General and Community Neurologist.”

39. Throughout the launch from October 2022 to over a year later, in November 2023, Defendants thus lauded the success of the launch and the near- and long-term ability for Relyvrio’s growth while failing to warn of concerning trends in declining new subscribers and patient discontinuations that would temper that growth.

C. Amylyx Hid Key Numbers Of New Subscribers And Patient Discontinuations, Artificially Inflating Relyvrio's Commercial Success And Prospects.

40. Behind the scenes, however, former employees (“FE”) tell a different story: how Defendants conspired to hide the sharp decline in new patient subscribers and the high, early discontinuations, from the market.

41. FE1 was a sales representative for Amylyx and covered all main accounts in New York City, including Columbia and Mt. Sinai—a region in the top three largest geographies in the country for distributing and marketing Relyvrio. FE1 started in November 2022 and left the Company in May 2024. Before joining Amylyx, FE1 had decades of experience in the pharmaceutical sales industry.

42. FE2 worked at Amylyx from September 2021 to December 2023 as the Regional Business Director responsible for overseeing sales. Only five people held this title nationwide, and those five directors split oversight of the business in the U.S. FE2’s region amounted to the West Coast, including every state that touches the Pacific Ocean: California, Oregon, Washington, Alaska, Hawaii, Nevada, Utah, Montana, Wyoming, and Idaho. This large market amounted to approximately 25% of Relyvrio’s sales. FE2 had eight sales representatives reporting to FE2.

43. These former employees conclude “absolutely” that Defendants misled the market about Relyvrio’s “prescription rate,” that “the rate at which new patients were starting treatment with Relyvrio was decreasing,” as well as “discontinuations” thus “overstating Relyvrio’s” success and opportunities for growth. Specifically, as detailed below, Defendants (1) hid the data from the market on these key metrics, (2) knew new patient subscribers were declining rapidly across the launch and that initial demand only rode on an initial bolus of subscriptions, which Defendants knew would not, and could not, continue, thus overstating the potential for Relyvrio’s growth, and

that (3) unknown to investors, patients were discontinuing after mere weeks treatment, further inflating the ability of Relyvrio to enter untapped patient subscribers.

1. Amylyx Intentionally Structured Its Launch To Hide Data On New Prescriber Rates And Discontinuations From The Market.

44. Both former employees revealed how during the Relyvrio launch, Amylyx strategically obscured data on subscription counts and discontinuations from the market—and even internally among Amylyx’s own employees.

45. FE2 related how, “early” in the commercial launch, Amylyx “established a limited distribution model,” “where [the drug] was only going through a few specialty pharmacies, and [providers and patients] had to use Amylyx’s own patient services.” While “not a horrible thing” when viewed in isolation, FE2 related that it was “very well stated all along that the reason management wanted to use the limited distribution model and the specialty pharmacy model is that so [Amylyx] could control all the data.” Their distribution model involved “controlling costs and data and everything else, and “internally,” to “try to hide the data as much as they could.”

46. As a sales representative, FE1 confirmed this lack of transparency at Amylyx for data on number of subscribers or discontinuation rates. While FE1 joined Amylyx excited about the promised hopes of helping ALS patients, FE1 soon noticed “a lot of things I have seen with the company [Amylyx] that I have never seen with any other companies” in FE1’s 20-year experience. Shortly after joining, FE1 started to “question everything because a couple of things just didn’t make sense.” For one, FE1 only had sales numbers “for our own territories which never happened with any other pharmaceutical company, and I’ve been with pharma companies for two decades.” “We always had transparency as far as numbers, where you ranked compared to other people in the country, general numbers, discontinuation rates, everything.” But here “we had nothing [at Amylyx]; not even my manager had exposure to what was happening with the rest of

the country,” as “the numbers were not shared” internally. When FE1 asked a manager, Beth Kinsella, the Regional Business Director of the Northeast, about this significant deviation from standard commercial practice, the response was, “this is just how it is; it’s strange, but it’s just how it is.” Given these anomalous data-sharing practices among its own employees, FE1 “wouldn’t be surprised” if the Company deliberately “blocked analysts from seeing prescription data in the summer of 2023.”

47. Likewise, in FE2’s time as regional director at the Company, Amylyx “didn’t share data with them for other parts of the country” “and the reason that they give us, which is bulls**t, is that they don’t want it to be easily added up so that somebody outside could find out what’s going on.” As a result, FE2 would get data on FE2’s region but “wouldn’t get data on the other four regions.”

48. FE2 “doesn’t know how [Amylyx] got away with hiding data from analysts in the summer of 2023” during the Relyvrio launch, and FE2 believes “[t]hat’s why they didn’t want to give us the data”—“[t]hey didn’t want us giving it to the analysts; they didn’t want us to leak it” to the market.

49. Amylyx also stopped reporting new patient subscriber data to market research services, IQVIA and Symphony, in the summer of 2023. (Amylyx, Q3 2023 Earnings Call).

2. Amylyx Misled The Market About Declining New Patient Subscribers Rates And Potential Growth After The Initial Bolus.

a. **Mere Months After The Launch, New Patient Subscribers Were Flat After The Initial Bolus Ended.**

50. Defendants also knew that the demand and subscriber count would taper off significantly after the initial bolus. As FE1 found, that initial demand only lasted in the “first three

or four months” after the commercial launch, around February 2023. After that, there “no chance for growth.”

51. As FE1 explained, given the devastating nature of ALS—and the lack of any viable treatment options—when Relyvrio was first launched “you had all these patients anticipating this treatment” and “patients wanted to get on it” immediately. These patients anxiously were waiting for this therapy because they “are going to die in five years” and “if God forbid you have someone that you know that has ALS, and there is potentially this new medication that is coming out, everyone wanted to go on it.”

52. This reality of ALS led to the initial “bolus of patients” which “was overwhelming even for the company to triage all these prescriptions in the beginning.” But as the prescriptions stabilized after the bolus, FE1 saw that “there was no growth. *It might have grown 1% or 2%* because there were newly diagnosed patients, but generally it was flat throughout the country.” That makes sense because after the bolus, demand would be limited to just newly diagnosed patients, and ALS is an extremely rare disease.

53. Even within that small group of potential new patients, “not every single newly diagnosed patient wanted to get on any treatment,” FE1 said, “because it’s not a cure” and to “endure side effects without sure benefit was not desired by many.” Indeed, one of FE1’s prominent prescribing doctors at an ALS center said that around 40% of the doctor’s patients didn’t want to take Relyvrio. FE1 would repeatedly tell FE1’s manager, Beth Kinsella, the Regional Business Director of the Northeast, that “this product has no potential to grow. It’s not an antibiotic.”

54. FE1’s sales numbers showcase this steep decline in new patient adds. In FE1’s territory—one of the largest geographically and the most populated—FE1 had only an average of

10 new patients per month. In FE1's number one account (Columbia University), FE1 had 246 prescriptions, comprising about 66% of FE1's business. In Q4 of 2022 FE1 had 122 prescriptions, Q1 of 2023 went down to 44 scripts, Q2 was 27 scripts, Q3 went up to 33 scripts, and Q4 was 21 scripts. FE1 confirms that management knew about this stalled growth "Data is data. They knew everything was flat. I grew my territory 170%. If mine is flat, so is every other territory."

55. FE1 affirms that management knew about the numbers of new patient adds in real time. FE1 worked with reimbursement managers that "had a database" to track new patient subscribers. Such notification (or lack of notification) means that the Company had real-time information on who was starting and when, ensuring the Company was aware immediately of changes in new patient starts.

56. Moreover, Amylyx's public statements show that the prescriber base did not expand meaningfully during the launch. For instance, the same amount of doctors (80) accounted for half of all prescriptions in Q1 2023 and in Q3 2023. (Amylyx Conference Call Transcripts). As the FEs relate, this flat growth is unusual for a ("successful") launch-stage drug and conflicts with the Company's oft-stated ability to keep expanding Relyvrio's prescriber base.

57. FE2 confirms this knowledge within Amylyx. In late 2022, after the initial launch, "Jim Frates right hand guy in finance tells us what the [2023 sales] forecast is and what our goals are going to be" and that the forecast was "front loaded for the first quarter," and that he "wanted them to get more than half of the business in the first quarter of 2023." When FE2 asked if that meant if their goals would go incrementally down through the rest of the year, he said, "Yeah, I guess."

b. There Was No Potential For Growth With General Neurologists.

58. In addition, as Defendant repeatedly stated, the initial bolus and influx of subscribers was “concentrated” with patients from ALS centers, but Defendants assured investors that there were opportunities for growth by targeting patients treated by “general neurologists.”

59. As FE1 related, “that’s baloney, there is no patient that has ALS that is maintained by a general neurologist, general neurologists don’t even want to touch it. They diagnose it.” Rather, given “the complexity of the disease, the ALS Association will tell a patient that they should be seen by an ALS center because you have access to so many different services there.”

60. FE1 “attended every single investor call,” and “was in awe how [management] could say there is potential for growth with general neurologists.” “It’s like saying for a cancer patient there is potential to grow within internal medicine. There is no cancer patient who is going to be followed by internal medicine. It’s the same thing here. They were certainly misleading to investors, and they tried to cover it up.”

61. That the “commercial prospects [for expansion with general neurologists] were definitely overstated” is confirmed by FE1’s numbers. In FE1’s entire territory, FE1 only had two general neurologists that ever wrote a prescription for Relyvrio in the duration of the launch.

62. FE1 directly warned management about this dead-end promise. Around Q4 2024, FE1 was asked to get on a call on a Sunday with CEOs Joshua Cohen and Justin Klee. In FE1’s “entire 20-year career in pharma, I had never been asked to join a call on a Sunday.” As FE1 put it: “Basically, we were asked about the potential growth in our geographies with general neurologists and getting our thoughts on the potential.” FE1 was very local about the reality that general neurologists are a “dead end,” stating “99% of them said that if we do diagnose it, we will send them to an ALS center because it’s too complex of a disease for us to treat it.”

63. Yet after that, around January 2024, Amylyx hired “third-party sales reps” to go after general neurologists and brought in no new leads. FE1 related how “there was a total coverup when they hired these third-party sales reps. I wouldn’t even call them sales reps; they were just calling general neurologists to generate leads for us.” FE1 believes it was done to “continue the narrative, that the company still believed that this is the way to go and that there is business with general neurologists.” But as FE1 predicted, from when they came on board in January to March, FE1 had “not gotten even one lead from them.”

c. The Amylyx Sales Teams Could Not Meet Internal Quotas.

64. Given this initial bolus and the inability for meaningful growth, FE2 described how the sales teams would be given quotas that “were ridiculous” and “you would never be able to hit these quotas.”

65. That these quotas were “impossible” is confirmed by FE2’s experiences talking with representatives from direct competitor, Mitsubishi Tanabe Pharma America. Those competitor representatives stated that their target “goals were a lot lower than their goals [at Amylyx] and they [MT Pharma] were being told that they were blowing it out of the water.”

66. The reality, FE2 relates, was that management “were overpromising and underdelivering,” “so they were trying to motivate us to sell more, and they hoped that the motivation of us selling more would then eventually have us hit our numbers that they were selling to Wall Street.” FE2 theorizes that superiors were “lead[ing] by fear.” “Nobody was making target and that is not the norm in our industry. People usually make target or better, but we were making under target during a launch. It was ridiculous.” “All it was that we saw was all senior leadership arguing with each other, never giving us clear direction, telling us that we were never doing anything right, and anytime we asked questions or came to them with solutions, they would just get angry,” FE2 said.

67. At bottom, Amylyx, FE2 said, “took advantage of these desperate people and then the sh**show just continued.” Every quarter when the sales teams “didn’t meet goal,” “they [senior leadership] kept on inflating the goal.” FE2 said, “I felt like I was talking to a priest; the more questions I asked, the more I was told to just have faith.”

d. Management’s Rosy Statements About The Launch’s Sales Success Did Not Match The Internal Reality At The Company.

68. As FE2 related, while senior executives were portraying to the world how well they were doing with sales, “that wasn’t true.” “Our boss was basically pinning us against each other and telling us that we’re all doing s**t, that we need to do better and were underperforming” — “yet what they were telling Wall Street was that we were blowing out our goals.”

69. Yet another former employee (FE3) confirms this mismatch between the Defendants’ rosy public statements and the internal panic to make sales after the initial bolus ended. FE3 was at Amylyx from January 2022 to June 3, 2024 and worked as a sales training coordinator in the Company’s commercial department, training salespeople on the Relyvrio product. In this training role, FE3 focused on learning and development for their commercial team by building onboarding content, onboarding the entire field force and any other customer facing commercial colleagues, and maintaining a continuous learning implemented program to keep people up to speed and engaged on the information needed to sell the drug. While FE3 worked closely with the Head of Sales (Tim Lee) and reported to him early on when FE3 started at Amylyx, as FE3 was commercial training role (unlike FE1 and FE2) FE3 did not have direct “insight” into the selling data on new subscribers and discontinuations, but nonetheless witnessed the CEOs’ “mixed messages” delivered internally and publicly after the bolus ended.

70. FE3 related that around the “middle of 2023, we were getting some mixed messages.” “Being in the commercial department and knowing and being on the same team as the

Head of Sales, I do recall him [Tim Lee] always trying to get us in the training department to fill gaps and get involved, push numbers up with training and continuous learning and building the field's knowledge to try and fill those gap numbers," and "I got the sentiment from [Defendant Olinger], through him, [Tim Lee] that we needed to work on some stuff and really make sure the team was trying to drive home the numbers." On the other hand, "then we would hear the CEOs during the same period say that we're doing great, everything is great, and all 'rainbows and butterflies' kind of energy." In fact, after a regional meeting in that period, the CEOs spoke about how "well the company was doing" but "[c]oworkers at that meeting were asking if they should be worried," and "there were some rumblings" about this disconnect.

71. Shortly after that meeting, when FE3 was in a private meeting with FE3's boss, Laura Jamieson, the Global Head of Training and Development, and Tim Lee, FE3 brought something up: "I asked him, I know [Defendant Olinger] is saying this, but the CEOs are saying that. What is really going on? It was confusing." FE3 said that Lee "gave a very vague answer," and "basically said that there were things that needed to be addressed such as the number of discontinuations and that the CEOs' focus was on many other things. He beat around the bush, and it was confusing."

3. Defendants' Fraud Is Confirmed By Unethical And Toxic Tactics To Boost New Prescription Numbers After The Initial Bolus.

72. After the initial bolus ended around February 2023, the former employees also relate how Amylyx resorted to increasingly desperate, and futile, attempts to increase patient subscriptions at any cost.

a. Defendants Try A Desperate, Unethical “Quid Pro Quo” Scheme To Boost Growth.

73. After the bolus, FE2 recalls how Amylyx resorted to an unethical “quid pro quo” tactic in a desperate attempt to raise the prescription levels.

74. After the demand from the bolus ended, FE2 described how the sales teams would be given quotas that “were ridiculous” and “you would never be able to hit these quotas.” Given that FE2’s boss was “on the hook for not meeting these quotas,” he started to push Dave MacLeod, Head of Global Patient Services and Commercial Distribution, and Keith White, the Head of Market Access, to open up the distribution model, letting institutions distribute the drug so more people could get it and they could generate more revenue.

75. FE2 described this quid-pro-quo relationship whereby institutions that should have been focused on solely on patient care could enroll as distributors, thereby receiving fees that would normally go to supply chain intermediaries such as wholesalers and pharmacies. While this scheme appears to operate at a one-step removal from direct payments in exchange for higher prescribing, it nonetheless involves remuneration that is dependent on prescribing frequency. As such, the arrangement could run afoul of the Federal Anti-kickback Statute and the False Claims Act, both of which are intended to maintain the integrity of healthcare decisions.

76. FE2 went to Keith White and told him that FE2’s boss requested FE2’s top ten accounts where they could get more business if they allowed them to distribute the product—an inappropriate quid pro quo arrangement. As FE2 related, FE2’s superiors “were specifically asking if they could get more enrollments if they opened up the distribution model,” “which is a complete quid pro quo.” “I said to Keith that this is how it sounds: you guys are trying to get business by opening up the distribution model and specifically asking people, will you give us

more business if we let you distribute the drug? Will your doctors write more?” White diminished these ethical concerns, telling FE2 that FE2 simply “misunderstood.”

77. Undaunted, FE2 knew “there was no misunderstanding” as FE2’s superiors “sent a spreadsheet about it” to implement this quid pro quo strategy. Yet when FE2 tried to raise this ethical quandary to Head of Compliance, attorney Sue Dyer, along with the attached spreadsheet, Amylyx had erased FE2’s emails. This left FE2 “befuddled” because FE2 positively had those emails about the unethical practice, but they were missing from FE2’s inbox. “I will bet my life on it, and I know these emails existed.” Indeed, FE2 also describes a culture where if someone spoke out about Amylyx’s practices, they would be fired or ignored. The Human Resources Department “was constantly investigating things and turning a cheek along with Sue Dyer, our Head of Compliance.”

b. When Amylyx Failed To Meet Internal Sales Targets After The Bolus, They Played The Blame Game.

78. After the bolus, FE2 confirmed that when management “couldn’t get enough patients on the drug and generate enough revenue,” “they basically just blamed” a scapegoat for “a faulty system and faulty data.” Tim Lee, the Director of Sales, and Defendant CFO Frates “were always butting heads.” After the initial demand settled, “Frates would give Lee a forecast, and Lee would tell him it wasn’t possible.” Defendant Frates would then tell him, “do whatever you’ve got to do” to make the numbers work. In response, Lee would start telling us to do stuff that was completely unethical,” FE2 said. “Paying off doctors, paying doctors to be speakers, whatever.” “It’s the bulls*** of my industry.”

79. FE2 recalled how all Defendant Olinger’s five direct reports, Tim Lee, Director of Sales, John Landry, Director of Operations, Keith White, Director of Market Access, Dave MacLeod, Director of Patient Services, and Shauna Horvath, Director of Marketing, “were all in

charge of different parts of commercial, and they were constantly arguing with each other.” “They were all trying to point fingers between marketing, sales, operations, market access, and pricing,” “all saying it was someone else’s fault; nobody was working together.” After quarters of missed sales results, “they needed to blame somebody, so like what constantly happened, is the people who were hiding information would get together and figure out who to blame” for failing to meet internal sales targets after the initial demand and new subscribers tapered off.

4. Unbeknownst To Investors, But Not Defendants, Patients Were Discontinuing Relyvrio Early Into Treatment.

80. Throughout the launch from October 2022 to November 2023, Defendants repeatedly stated they could not see trends in patient discontinuation rates or how long patients would remain on Relyvrio as therapy. It was not until November 2023 that Defendants revealed discontinuation problems, purportedly that patients were “discontinuing” after being on treatment “after six months.”

81. But both former employees reveal that patient discontinuations were occurring mere weeks after starting the drug—and certainly soon enough for Defendants to be aware of these trends. According to FE1, in reality, patients “were discontinuing treatment *within the first month or two*”—“it was much sooner than six months.” FE2 likewise reiterated that senior leadership were “absolutely” overstating Relyvrio commercial prospects to the public given “that people were discontinuing the drug before six months.”

82. FE1 also confirmed that management would track these discontinuations in near real time. For one, FE1 worked with reimbursement managers that “had a database where they could track the last shipment and they would follow up with the patient directly” if they did not refill the prescription to confirm the discontinuation. In addition, FE1 says that management “knew this was an issue [discontinuation rates] because there were a lot of things being done to

mitigate the GI side effects” behind many dropouts, including training for medical science liaisons about how to address discontinuations in real time due to negative side effects.

83. This attempted intervention on discontinuations was widely discussed on conference calls in FE1’s region. The “number one” such effect was diarrhea and “if you’re in a wheelchair you’re pretty much dependent on someone caring for you,” and “if someone has to wipe you every 30 minutes or hour because of that it becomes very uncomfortable, and patients would discontinue even within that first month.” Given that these discontinuations were such an issue, Amylyx created a PDF for providers on what to do and what other medications they could use for the GI side effects.

84. Understandably, many patients discontinued because they did not see any positive results from the drugs. If they continued to progress with their disease and still had horrible symptoms, “it wasn’t worth it.” FE2 confirms that “all the sales and medical people all knew why the drug wasn’t being used and they [senior leadership] didn’t want anything to do with that; all they were telling us was that . . . [the] Phoenix [trial] is going to prove it and there are 30,000 patients who need this drug, so you guys need to figure out a way to get them to use it.”

5. By Hiding These Discontinuation Trends, Defendants Overstated The Demand For, And Projections Of, Patient Prescriptions.

85. While consistently lauding the potential for new and growing subscriptions, this hidden discontinuation trend also obscured the truth about the reported subscriptions and likely future patient subscriptions. In other words, revealing only “net adds” of patients without also including the discontinuation rates obscured the remaining “runway” for growth.

86. As FE2 reported, Defendants Klee and Cohen “kept saying there were 30,000 patients in the United States that should be treated with Relyvrio,” implying there was ample room for growth from the reported numbers between 1,000 and 3,800. Yet when the initial bolus of

patients was at its peak, “we already had 9,000 patients on the drug” and “we already had a third of the business.” Despite this, Defendants Klee and Cohen “were saying that we were underperforming,” so FE2 at the time “didn’t know what the disconnect was.” FE2 believes the failure to consider discontinuations in this reporting data rendered the current numbers and future projections of patient subscribers “way off.”

D. Materially False and Misleading Statements Issued During the Class Period.

87. The Class Period begins on November 11, 2022. On November 10, 2022, during after-market hours, Amylyx issued a press release announcing the Company’s Q3 2022 financial results. That press release quoted Defendants Cohen and Klee, who stated, in relevant part:

We are thrilled that RELYVRIO . . . [is] now available to people living with ALS in the U.S. . . . and ***we are encouraged by . . . the rate of new prescriptions for this important new therapeutic option.*** We continue to work expeditiously during the early stages of our commercial launch to ensure every eligible person living with ALS will gain access as quickly and efficiently as possible.

(Emphasis added.)

88. That same day, also during after-market hours, Defendants hosted a conference call with investors and analysts to discuss Amylyx’s Q3 2022 results (the “Q3 2022 Earnings Call”). During his prepared remarks on that call, Defendant Klee stated, in relevant part:

Given we are only a few weeks into the launch in the U.S., it is too early to discuss specific expectations. ***But we are encouraged by the initial engagement with both physicians and with people living with ALS.***

(Emphasis added.)

89. Likewise, during his prepared remarks on the Q3 2022 Earnings Call, Defendant Cohen stated, in relevant part, that “[w]e are excited about the strong initial interest that we are seeing only a couple of weeks into launch” of Relyvrio.

90. During her prepared remarks on the Q3 2022 Earnings Call, Defendant Olinger represented, in relevant part:

In the days and weeks following the FDA's approval of RELYVRIO on September 29, ***we immediately started receiving enrollments and prescriptions through the Amylyx Care Team***, and have heard very positive feedback from physicians in the ALS community about the level of support we are providing. Importantly, on October 24, the first shipment of RELYVRIO from one of our specialty pharmacies was sent to a person living with ALS earlier than we had originally anticipated.

In regard to interest in RELYVRIO, we are seeing a solid initial bolus, including an encouraging number of products enrollment forms and prescriptions coming into the Amylyx Care Team. This initial excitement has also been widespread across the country, and not limited to one geography or group of physicians. The field teams have engaged with clinicians throughout the country, and the feedback from those serving the community has been positive.

(Emphases added.)

91. During the question-and-answer ("Q&A") portion of the Q3 2022 Earnings Call, in response to an analyst question regarding "how long [Defendants] expect patients to stay on drugs in [Amylyx's] model," Defendant Cohen answered, in relevant part:

[W]hen it relates to time on therapy, we haven't given specific guidance as to time on therapy for our product. But I can say we've done some research on past products . . . where we see in the ballpark of a year – on average or median. That being said, one of our hopes with having a really robust education and patient support function is that ***we'll be able to educate about the benefits of staying on therapy as well.***

(Emphases added.)

92. This statements in ¶¶ 87-91 from November 11, 2022 were false and misleading and omitted material information given Defendants were aware that the "initial" demand was due to a temporary "bolus" of patients that would shortly stabilize, offering no meaningful opportunity for further "growth."

93. On February 14, 2023, Amylyx filed a current report on Form 8-K with the SEC, stating, in relevant part, that “[t]he Company **has observed higher demand for RELYVRIO in the U.S. than initially anticipated pre-launch and, as a result, expects to meaningfully exceed fourth quarter and full-year 2022 Wall Street research analyst consensus estimates for revenue.**”

94. This statement in ¶ 93 was false and misleading and omitted material information given: (1) the “higher demand” was due to an initial, temporary bolus of patients that, by this time, had stabilized, offering no meaningful opportunity for further growth., and (2) at the time, Defendants already were aware that high, undisclosed discontinuation rates were occurring, undermining the commercial potential for the launch.

95. On March 13, 2023, Amylyx issued a press release announcing its fourth quarter and full year (“Q4/FY”) 2022 financial results. That press release quoted Defendants Cohen and Klee, who stated, in relevant part:

2022 was an exceptionally exciting year for Amylyx, culminating with the approval of RELYVRIO in the U.S. ***Our commercial launch is off to a strong start, and we are encouraged by the engagement we have seen from physicians, people living with ALS, and payors . . . [W]e remain focused on our efforts to engage stakeholders throughout the ALS community as we work to drive the broadest coverage possible for this important new therapeutic option.***

(Emphasis added.)

96. That same day, Defendants hosted a conference call with investors and analysts to discuss Amylyx’s Q4/FY 2022 results (the “Q4/FY 2022 Earnings Call”). During his prepared remarks on that call, Defendant Klee stated that “[s]ince the approval, ***we have seen strong interest in RELYVRIO and we are encouraged by the early success of our commercial launch.***”

97. Likewise, during his prepared remarks on the Q4/FY 2022 Earnings Call, Defendant Frates stated:

We're pleased to share that at this point in our launch we're meaningfully ahead of our expectations and encouraged by the interest and demand we've seen from the ALS community. [Defendant Olinger] will share some of the important early metrics that we're tracking, which should help you model our near-term opportunity and the total addressable market for the longer term, but first I'll summarize Q4.

Net product revenues were \$21.9 million for the quarter and \$22.2 million for the year with the vast majority of that revenue from the [U.S.] As you'll hear from Margaret in a few minutes, *we're seeing robust demand from the ALS community.* Gross-to-net adjustments were approximately 18% in the quarter and in-line with our expectations. We expect gross-to-net to remain in the 15% to 20% range for the year starting at the higher end of that range in Q1 due to the annual reset of co-pays and deductibles in Medicare Part D reenrollment as of January 1st.

(Emphases added.)

98. During her prepared remarks on the Q4/FY 2022 Earnings Call, Defendant Olinger described the continued “uptake” in patient subscribers and the “significant opportunity for growth”:

[W]e are seeing our efforts *yield strong results and have observed rapid uptakes* on the FDA’s approval on September 29. There were just over 1300 people living with ALS on RELYVRIO in the [U.S.] at the end of 2022, *and uptake has continued since then.*

We remain optimistic about our ability to continue growing from here as we believe people with ALS and their clinicians are eager to learn about and try new treatment options. By the end of this quarter we believe we are on our pace to roughly double the amount of people on RELYVRIO on a net basis.

On the clinician side, we are encouraged by the prescriptions coming from the top ALS doctors and key ALS centers, but there is still significant opportunity for growth....

Another notable part of our launch is the interest that we are seeing across the spectrum of people living with ALS when we look at the times of initial diagnosis. We are encouraged that regardless of the time since diagnosis, people with ALS are interested in and gaining access to this important new treatment. In other words, we *are seeing people on RELYVRIO who have been newly diagnosed as well as others who have been diagnosed for more than three years.*

As we look throughout the rest of the year, our team remains vigilant in our efforts to educate ALS centers *and look forward to educating the general neurologist.*

We believe we have a large untapped opportunity for additional growth as we conduct ongoing research outreach. We remain committed to driving access with and support to every eligible person living with ALS who can benefit from treatment.

(Emphases added.)

99. During the Q&A portion of the Q4/FY 2022 Earnings Call, in response to an analyst question regarding “whether the patient numbers at the end of December . . . was approaching about 1500 to 2000,” Defendant Frates touted:

[W]e're seeing the demand increase, right? And again, [Defendant Olinger] mentioned there were 1300 patients on drug at the end of 12/31 and at the end of Q4, and we’re looking at roughly doubling that as we get to the end of March, so 2,600 patients plus or minus.

* * *

And I think I guess I would just say, ***we're off to a really good launch.*** I think we’re probably going to be able to more than double our revenues in Q1. I’d say we’d be closer to tripling our revenues than we are to doubling our revenues, but wouldn’t want to give more guidance than that.

(Emphases added.)

100. During the same Q&A, in response to an analyst question regarding “the centers that are responsible for the book of scripts . . . to get a sense as to the inquiries or the queue of patients across the broader ALS population” and “to get a sense of the breadth of awareness on whatever metric you guys can provide,” Defendant Olinger stated:

[T]here's about 2700 physicians that prescribe for ALS, which is our broad target audience. During the first quarter, we are heavily focused on the top ALS centers and the top 500 prescribers of which 55% of them have written a prescription for RELYVRI in the fourth quarter. So that continues to be our focus. There's a lot of opportunity that remains in those top prescribers, but also a lot of patients are being seen by the general neurologists out in the communities, and that's clearly our next runway that we have to continue to penetrate this market much more broadly than we have to date.

(Emphases added.)

101. On the same call, in response to an analyst question regarding the pace of patients starting treatment with Relyvrio and “a sense for how we think about the pace of starts after” the first quarter (“Q1”) of 2023, and whether Defendants “expect this kind of 1300 patients per quarter to be kind of a sustainable rate or should we expect the pace of new starts to kind of start to decline thereafter”, Defendant Olinger again assured investors about the “long runway” for growth:

So we just want to reiterate, we are very pleased with the growth we’re seeing in the second, in Q4 of 2022 and so far this year. And we are -- and things are going really well. We’re seeing an initial bolus in demand. And to be honest with you, we just don’t know how big this bolus will be or how long it will last. But we expect continued growth and interest in demand as the initial prescribing has been relatively concentrated as I mentioned. We have a large untapped opportunity to build on in our ongoing outreach and education and efforts. We really see that we have a lot of runway ahead of us.

(Emphases added.)

102. In response to the same analyst question, Defendant Klee reiterated:

*[A]nd just one more point, as [Defendant Olinger] emphasized the demand, I think that’s on the plus side, right? **We’re seeing early demand. It’s very concentrated so far so we have a lot of breadth and depth to continue to look forward to, I think as we expand this product.***

103. Likewise, in response to an analyst question regarding “what the launch curve might look like with an initial bolus and then steadyng out until we get to steady state” and “[h]ow [Defendants] are . . . thinking about it now that [they]’re in the market and seeing kind of the demand that [they]’ve had thus far,” Defendant Olinger again lauded the progress of the launch the future ability to grow subscribers:

*[I]n terms of the slope of the ramp, to your point, it is very early months of the launch, **but we are seeing very encouraged levels of interest from both people living with ALS and clinicians** and we said that Q4, we ended with 13 [later changed by the Company to “1300”] people on therapy. We expect to double that by the end of Q1. And again, I just want to reiterate to **everybody that is on a net basis, which should give you a good sense of how the launch is progressing**. And while we do have that initial bolus of demand, we don’t know how big and how*

long that will last, ***we do really are very confident in the long runway we have ahead of us.***

So our focus remains on the 1,300 patients that are on therapy today ***and keeping them on therapy.*** And then also, we're very encouraged by the insurance favorability that we're seeing, while it's only a third at this point we have very broad access to date, and we're encouraged at the future.

(Emphases added.)

104. Also on March 13, 2023, Amylyx filed an annual report on Form 10-K with the SEC, reporting the Company's financial and operational results for the quarter and year ended December 31, 2022 (the "2022 10-K"). In discussing Amylyx's commercialization of AMX0035 (Relyvrio), the 2022 10-K stated, in relevant part:

Since obtaining regulatory approval, we have seen strong interest in AMX0035, and we are encouraged by the early success of our commercial launch.

* * *

When shown a target product profile for AMX0035, the majority of ALS specialists and neurologists with whom we spoke are open to utilizing it in early-to-mid-stage patients, with some also stating the potential for use in late-stage patients.

(Emphases added.)

105. Moreover, in discussing Amylyx's strategy to "[e]ffectively and efficiently commercializ[e] RELYVRIO for ALS in adults in the U.S.," the 2022 10-K touted the Company's "***commercial capabilities***, coupled with our understanding of the ALS patient and medical community," as a key element that "***will enable us to successfully commercialize RELYVRIO for ALS in the U.S.***" The 2022 10-K also represented that "***as we begin to commercialize RELYVRIO in the U.S. . . and learn more about market dynamics . . . our view of our products' initial potential market opportunity will become more refined.***"

106. The March 13, 2023 10-K also contained disclosures under Item 7 requiring information called for under Item 303 of Regulation S-K [17 C.F.R. § 229.303], “Management’s Discussion and Analysis of Financial Condition and Results of Operations” regarding the Relyvrio launch:

The successful development and commercialization of AMX0035 [Relyvrio] and any future product candidates is highly uncertain, due to the numerous risks and uncertainties associated with product development and commercialization, including the following:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical trials for separate indications we decide to pursue;
- raising necessary additional funds;
- the progress of the development efforts of parties with whom we may enter into collaboration arrangements;
- our ability to maintain our current development activities and to establish new ones;
- our ability to establish new licensing or collaboration arrangements;
- the successful initiation and completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to Health Canada, the FDA or the EMA, or any other comparable foreign regulatory authority;
- the receipt and related terms of regulatory approvals from applicable regulatory authorities, including our marketing authorization with conditions from Health Canada for ALBARIOZA and the post-marketing requirements from the FDA for RELYVRIO;
- the availability of drug substance and drug product for use in production of AMX0035;
- establishing and maintaining agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing;
- our ability to obtain and maintain patents, trade secret protection and regulatory exclusivity, both in the U.S. and internationally;
- our ability to protect our rights in our intellectual property portfolio;

- the commercialization in Canada and the U.S. of AMX0035 (known as ALBARIOZA in Canada and RELYVRIO in the U.S.) and in other potential jurisdictions, if and when approved
- obtaining and maintaining third-party insurance coverage and adequate reimbursement;
- the acceptance of AMX0035, if approved, by patients, the medical community and third-party payors;
- competition with other product; and
- a continued acceptable safety profile of our therapies in pre-approval market access programs or in commercial access following approval.

A change in the outcome of any of these variables with respect to the development of AMX0035 or any future product candidates could have a significant impact on the cost and timing associated with the development of our product candidates. We may never succeed in obtaining or maintaining regulatory approval for AMX0035 or any future product candidates.

107. Appended as exhibits to the 2022 10-K were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 (“SOX”), wherein Defendants Cohen, Klee, and Frates certified that “th[e] 2022 10-K] does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by th[e]” 2022 10-K, and that “the financial statements, and other financial information included in th[e] 2022 10-K], fairly present in all material respects the financial condition, results of operations and cash flows of [Amylyx] as of, and for, the periods presented in th[e]” 2022 10-K.

108. This statements in ¶¶ 95-107 delivered on March 13, 2023 were false and misleading and omitted material information given: (1) at the time, Defendants knew the “robust demand” was due to an initial, temporary bolus of patients that, by this time, had stabilized, offering no meaningful opportunity for further “significant growth,” (2) there was no growth

potential for “newly diagnosed” patients with ALS, (3) “general neurologists” did not provide an avenues of “untapped growth” for new subscribers, (4) Defendants already were aware that high, undisclosed discontinuation rates were occurring, undermining the commercial potential for the launch, and (5) those hidden discontinuations inflated the “runway” for the stated net patient subscribers.

109. On April 18, 2023, Defendants attended a virtual conference addressing Relyvrio. In response to a question asking about the “first launch quarter of sales, [of a] very encouraging start” and to “talk[] through some of the metrics that you’re looking for in terms of building upon this strong first quarter” and “how you expect these things to kind of evolve and continue to build over the course of 2023?,” Defendant Cohen responded:

We had roughly 1,300 patients on drug at the end of the year. By the end of this quarter, we expect to roughly double that. And we believe most of that was fairly concentrated prescribing from some of the very specialty centers. We believe there's a lot more to educate to a lot more people to bring onboard those potential prescribers to keep growing that.

And I'll say it too, it feels like it's been – we've been out there for a while, but launch was only pretty recently. Until there's only been so much time for all these sites to get on board. So, *I think there's even a lot of potential still at some of the sites that have had just started by the time of the fourth quarter or the first quarter, still a lot more patients to get on...*

Quite interestingly, we've just seen very broad -- at least as of last report, *we've seen very broad prescribing with people, both who are very recently diagnosed and people who have had the disease more than three years. So, I think, again, we continue to see a pretty broad base for who's taking RELYVRIO and getting prescribed that.*

(Emphases added.)

110. Defendant Cohen’s statements in ¶ 109 from April 18, 2023 were false and misleading and omitted material information given: (1) at the time, Defendants knew the “robust demand” was due to an initial, temporary bolus of patients that, by this time, had stabilized,

offering no meaningful opportunity for further “growth” from “concentrated ALS centers,” and (2) there was no growth potential for “newly diagnosed” patients with ALS, (3) Defendants already were aware that high, undisclosed discontinuation rates were occurring, undermining the commercial potential for the launch, and (4) those hidden discontinuations inflated the “potential” growth for the stated net patient subscribers.

111. On May 11, 2023, Amylyx issued a press release announcing its Q1 2023 financial results. That press release quoted Defendant Cohen stating:

During [Q1], we made significant progress on our commercial launches of RELYVRIO in the U.S. . . . as we advanced our goal of ensuring efficient access for every eligible person living with ALS. ***We continue to see strong engagement and interest from physicians and the ALS community*** and are encouraged that the vast majority of payors who have published formal policy decisions are providing broad access to RELYVRIO.

(Emphasis added.)

112. That same day, Defendants hosted a conference call with investors and analysts to discuss Amylyx’s Q1 2023 results (the “Q1 2023 Earnings Call”). During his prepared remarks on that call, Defendant Klee likewise represented:

In [Q1], we saw a continued high level of interest from the ALS community and RELYVRIO broadened insurance coverage, and high levels of engagement with our Amylyx care team, also known as act, just two quarters into launch over 10% of the approximately 29,000 people living with ALS in the US are now on RELYVRIO. ***Even with that success in our first six months, we have more to do.*** There remain many more 1000s of people living with ALS in the US and at least 200,000 people living with ALS globally. ***We are still in the early stages of our journey, and our team remains hard at work.***

* * *

Our commercial ramp in the U.S. . . is proceeding very well . . . And we achieved our first quarter of profitability in just the second quarter of our commercial launch in the U.S.

(Emphases added.)

113. On the same call, Defendant Frates similarly related:

We're encouraged by the strong interest in demand we continue to see from the ALS community. From a financial point of view, our business [is] strong. Net product revenue were \$71.4 million for the quarter, compared to net product revenue of \$21.9 million for the fourth quarter of 2022 with the vast majority of that revenue from the [U.S.]

* * *

I want to pause a moment on our overall financial results ***with the strong demand for RELYVRIO driving near term profitability ahead of our expectations. We want to reiterate our long term financial goals driving top line revenues as RELYVRIO become standard of care, growing profitability for our investors, and investing in a pipeline that has the potential to provide much needed treatments for neurodegenerative diseases. We're well-positioned to build a profitable financially strong organization for the long term We're currently in a position to fund the programs, we discussed it without the need to raise additional capital.***

(Emphases added.)

114. During her prepared remarks on the Q1 2023 Earnings Call, Defendant Olinger echoed these sentiments:

We are seeing continued interest and demand for RELYVRIO. As of March 31, there were roughly 3000 people on RELYVRIO in the US more than double the number of people on RELYVRIO at the start of the quarter. We are pleased that this many people have gained access to our important treatment.

I think it's worth spending a minute to provide some additional context on the strength of our launch. While we knew there was pent up demand, ***the fourth quarter and first quarter, were still well ahead of our expectations.*** The rate of net patient's [indiscernible] has begun to moderate as expected. ***However, we still see significant demand for people living with ALS, and physicians alike. Importantly, we still have plenty of room for growth, both at the top ALS centers, and the broader neurology community.***

Now, let me run through a few metrics that show our progress, but also the growth opportunities ahead of us. By the end of the first quarter, approximately 65% of the top 500 US prescribers and approximately 95% of the key ALS centers had prescribed RELYVRIO out to at least one person since launch. ***Prescribing remains fairly concentrated,*** with roughly 80 prescribers mostly at major ALS centers, representing approximately half of all RELYVRIO prescriptions during the quarter. While we are encouraged with these data points, ***we see an opportunity for***

broader and deeper uptake of key ALS centers, and the opportunity to continue to penetrate the group of top prescribers.

...“[w]e continue to see a wide range of people living with ALS in terms of time sense initial diagnosis, interested in and gaining access to RELYVRIO.”

(Emphases added.)

115. During the Q&A portion of the Q1 2023 Earnings Call, in response to an analyst question regarding “the [moderated] rate of pace” of new patients for Relyvrio and “expectations going to perhaps the second quarter,” Defendant Olinger stated:

[W]e continue to be incredibly pleased with our launch today [I]f I could just reiterate a few key points, we ended the quarter with roughly 3000 patients, again, double what we started with at the beginning of the quarter.

And that's about 10% of the 29,000 patients living with ALS. So not surprisingly, our net patient ads can't double forever. So in Q2 we are expecting the number will be lower than what we delivered in Q4 and Q1. I think more importantly, we continue to see significant interest in demand for RELYVRIO both from patients and HCP. And we have a tremendous opportunity for us to grow both in depth and breadth at all the key ALS centers[.]

(Emphases added.)

116. Similarly, in response to another analyst question regarding “the rate of net patient ads . . . beginning to moderate” and whether Defendants “[c]ould . . . perhaps provide any updated views on how big this initial bolus of patients could be” and “how long it could last before [Defendants] achieve a steady state trajectory of new starts,” Defendant Olinger stated:

Regarding the bolus, it's really too early to tell when the bolus will finish. But what I can say is that we know in Q4 and in Q1, we did see that high level of demand due to the pent up demand that we had. And they were quite frankly, even ahead of our expectations. So we have begun to see the rate and new patient ads moderate. But again, I want to reiterate, we have a tremendous opportunity for growth, because even within the key accounts that we penetrated. And just remind you of some of the metrics, we said 95% of all the key ALS centers have prescribed for at least one patient every account, you see one account, you see one account. It's typical rare disease. So some accounts are highly penetrated. And some accounts have a great deal of room ahead of us to penetrate. And we really have just started to get out into the broader neurology community. So again, we

see tremendous growth ahead of us to serve all the remaining patients that are depending on us.

(Emphases added.)

117. In response to yet another analyst question during the Q1 2023 Earnings Call regarding “what you’re seeing in terms of start forms versus net ads,” whether Defendants “can talk about the trend you’re seeing there,” and whether Defendants could provide “any color on duration of therapy so far, or any dropouts that you’re seeing,” Defendant Klee largely deflected the question, answering:

So we’re not providing any guidance on the number of patients for the quarter again, I’ll just go back to, we think our net patient adds, they can’t double forever. So we’ll be lower in Q2 than we’ve been able to deliver in Q4, Q1 because we believe that was the initial pent up demand. *Again, we don’t know, when that bolus will be over. So it’s hard for us to really give any guidance on that. In terms of duration of treatment, it’s really too early in the launch to give that I mean, the first patients who started on therapy, we’re basically at the end of October, beginning of November. So they really haven’t been on therapy long enough for us to give, any, any clarification there. In terms of discontinuation rates, that’s sort of similar as well. People just haven’t been on therapy long enough...*

(Emphasis added.)

118. Also on May 11, 2023, Amylyx filed a quarterly report on Form 10-Q with the SEC, reporting the Company’s financial and operational results for the quarter ended March 31, 2023 (the “Q1 2023 10-Q”). The Q1 2023 10-Q contained the same statements as referenced in ¶¶ 104-107, *supra*, assuring investors that Defendants’ understanding of Relyvrio’s commercial prospects, including, presumably, its prescription rate, would become more accurate with time, and that investors could, therefore, trust Defendants’ representations concerning Relyvrio’s commercial prospects and prescription rate.

119. Appended as exhibits to the Q1 2023 10-Q were substantively the same SOX certifications as referenced in ¶ 107, *supra*, signed by Defendants Cohen, Klee, and Frates.

120. This statements in ¶¶ 112-119 from May 11, 2023 were false and misleading and omitted material information given: (1) at the time, Defendants knew that the “significant demand” was due to an initial, temporary bolus of patients that, by this time, had stabilized, offering no meaningful opportunity for further “plenty of room for growth,” (2) at the time, contrary to their representations, Defendants knew the “initial bolus” was over, (3) there was no growth potential for “newly diagnosed” patients with ALS, (4) outside the “concentrated ALS centers,” the “broader neurology community” did not provide opportunity for future growth, (5) Defendants already were aware that high, undisclosed discontinuation rates were occurring, undermining the commercial potential for the launch, and (6) those hidden discontinuations inflated the “ramp” for the stated net patient subscribers.

121. On August 10, 2023, Amylyx issued a press release announcing its second quarter (“Q2”) 2023 financial results. That press release quoted Defendants Cohen and Klee, who stated, in relevant part, that “*[w]e made strong and steady progress on our commercial launches in [Q2], supporting people living with ALS with increased access to RELYVRIO.*” (Emphasis added.)

122. That same day, Defendants hosted a conference call with investors and analysts to discuss Amylyx’s Q2 2023 results (the “Q2 2023 Earnings Call”). During his prepared remarks on that call, Defendant Klee stated, in relevant part:

In [Q2], we made significant progress in bringing RELYVRIO . . . to people with ALS in the US[.]

* * *

Let me walk you through our progress. *Our commercial organization is off to a strong start . . . as evidenced by the strong and steady demand we saw in [Q2].* As of June 30, 2023, there were roughly 3,800 people on RELYVRIO in the US, up from roughly 3,000 people on RELYVRIO as of March 31, 2023 and just over 1,300 at the end of 2022.

(Emphases added.)

123. Similarly, during his prepared remarks on the Q2 2023 Earnings Call, Defendant Frates stated, in relevant part:

We're encouraged by the strong interest and demand we continue to see from the ALS community in the second quarter. From a financial point of view, our business remains strong.

Net product revenues were \$98.2 million for the quarter, compared to net product revenue of \$71.4 million for the first quarter of 2023, with the vast majority of that revenue coming from the [U.S.]

(Emphasis added.)

124. Likewise, during her prepared remarks on the Q2 2023 Earnings Call, Defendant Olinger represented:

During [Q2], interest in and demand for RELYVRIO continued to build at a steady pace from both those that are newly diagnosed and people who have been living with ALS for years.

* * *

Now, let me run through a few key metrics that demonstrate our progress and growth opportunities ahead of us. ***Prescribing remains fairly concentrated with just over 80 prescribers mostly at major ALS centers representing approximately half of all RELYVRIO prescriptions at the end of the quarter.***

We are encouraged by the level of interest among this group and believe that we have an opportunity for growth as we bring our message to more prescribers and deepen our relationships within these key ALS centers.

(Emphases added.)

125. During the Q&A portion of the Q2 2023 Earnings Call, in response to an analyst question regarding “what are you seeing with respect to . . . discontinuation rates” and whether Defendants “[a]re . . . seeing any emerging trends with respect to the primary reason for discontinuation,” Defendant Olinger stated:

[A]s a reminder, we report on net patients on therapy. So this is inclusive of any discontinuation. We are really pleased with our ability to serve the roughly 3,800 net patients on RELYVRIO at the end of Q2. I would say it's really too early to see any long-term trends at this point in our launch.

(Emphasis added.)

126. Likewise, in response to an analyst question regarding whether Defendants “have any better sense of the size of the patient bolus at this point” and the discontinuation rates, particularly “among the early patients t[hat] have received [the] commercial drug in 4Q of last year [who are] presumably some of the[] patients . . . would have been on drug for at least six months now,” and whether Defendants could “provide any color as to what percent of them are still on therapy at this point again just among the patients who started in 4Q,” Defendant Olinger largely deflected the question, stating:

Maybe I'll just start with your question regarding the bolus. We continue to be pleased that the interest in and demand for RELYVRIO, continues to be as at a very strong pace and I think importantly includes a mix of both newly diagnosed patients and people who have been diagnosed and living with ALS for many years.

Again at the end of Q2, we had roughly 3,800 net patients on therapy up from roughly 3,000 patients in Q1 and just over 1,300 in Q4. *So we really believe that at this point in time RELYVRIO is really starting to become a foundational therapy in ALS and meeting a really high unmet need for this patient community which is obviously our mission and what we've been focused on for some time.*

As far as the growth opportunities which is equally important to us we see several different opportunities ahead of us. First *the prescribing remains really concentrated* with the 80 prescribers mostly at the major ALS centers where our focus was at the beginning of launch representing about half of all RELYVRIO prescriptions this quarter. *We're also encouraged that the level of interest among this group and believe that we have a large opportunity for growth ahead of us.* As we bring our messaging to more prescribers and deepen our relationships within those key centers. And I think importantly with those prescribers be much more prolific in their prescribing which I think is an important part.

And second *we have a really large untapped opportunity for growth outside of this group.* As I mentioned, we were heavily focused on the key ALS centers at launch. We're continuing to expand our outreach and educational efforts more broadly because we believe it's critically important that everybody is aware that RELYVRIO is the first-and-only product to have both function and survival demonstrated in the clinical trial and we believe we can change the paradigm for treatment moving forward. And maybe *just to answer your second question on*

discontinuation, again, we're only going to be reporting on net patient numbers for a quarter. But indeed, I think it's important to reflect that the first cohort of patients who started on therapy at launch many of those who have been really fairly progressed early on. So I think we're going to see the dynamic of the patients change over time. So it's a little too early to really give any trends there.

(Emphases added.)

127. Similarly, when asked by an analyst on the same call regarding “what kind of trends you’re seeing you saw in July,” Defendant Frates largely deflected the question, stating:

[I]n terms of July, I think we'll comment on the July trends when we report our quarterly results for Q3. But I think our business is -- with now three quarters under our belt, we're all starting to get a chance to see what our business is like moving forward. But we won't be giving specifics on July at this stage.

(Emphasis added.)

128. Presumably dissatisfied with the Individual Defendants’ responses regarding what they observed vis-à-vis prescription rate trends for Relyvrio, as well as the retention rate of patients using Relyvrio for ALS treatment, yet another analyst attempted to elicit some color on these issues on the Q2 2023 Earnings Call. However, in response, Defendants Klee and Olinger again largely deflected the question:

[Analyst]

Thanks so much. Congrats on the quarter. Just two questions. One maybe another way to ask a question that people seem to be trying to get at. Do you have any color on -- or can you provide any color on kind of new prescription trends versus refill trends? Any metrics you can provide there and how that’s evolved?

* * *

[Defendant] Klee

So I’ll start and then have [Defendant Olinger] join in too. So again, we’re three quarters into launch. We have roughly 3,800 net people on treatment as of the end of Q2 which we’re very pleased about. I mean, that’s 3,800 people with ALS we’re helping. *But that means that there's many, many more people that we'd like to help as well.*

But I think we all here are constantly reminded of the mission at hand. And I think the ALS market in many ways is unique. And it's because it's a large rare disease, there's a huge unmet medical need. And historically there have been few treatment options.

And so I think the way that we've thought about our business, as Margaret was sharing, is to focus on the ALS specialists, and then continuing to look to broaden out. And so I think as we look at our prescription numbers, where our people have focused is where we're seeing the prescriptions as well.

And then [Defendant Olinger], I'll invite you to share any more details on that.

[Defendant] Olinger

Yeah. As we've indicated heavily focused at launch which I think was the right strategic decision to focus on the key ALS centers where the majority of ALS patients are actually treated.

However, there's also a number of ALS patients that are treated outside of ALS centers for multiple reasons, either they can't transport, they can't get there at a reasonable time and it's -- they typically need to go there every quarter to see the multidisciplinary care.

There are a number of General and Community Neurologist, that are equally important to be educated and that's where we're expanding our focus. And we are continuing to increase our penetration and reach out to those, what we call our Tier A or B targets.

And we're just going to continue to work on that expansion moving forward, because it's really important for us that every physician who treats an ALS patient is educated about the significant RELYVRIQ benefits that we can bring to be able to serve this patient community optimally.

(Emphases added.)

129. Also on August 10, 2023, Amylyx filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operational results for the quarter ended June 30, 2023 (the "Q2 2023 10-Q"). The Q2 2023 10-Q contained the same statements as referenced in ¶¶ 104-107, *supra*, assuring investors that Defendants' understanding of Relyvrio commercial prospects, including, presumably, its prescription rate, would become more accurate with time,

and that investors could, therefore, trust Defendants' representations concerning Relyvrio's commercial prospects and prescription rate.

130. Appended as exhibits to the Q2 2023 10-Q were substantively the same SOX certifications as referenced in ¶ 107, *supra*, signed by Defendants Cohen, Klee, and Frates.

131. This statements in ¶¶ 121-130 from August 10, 2023 were false and misleading and omitted material information given: (1) at the time, Defendants knew that the "significant demand" was due to an initial, temporary bolus of patients that, by this time, had stabilized, offering no meaningful opportunity for further growth or a "strong pace" of demand, (2) at the time, contrary to their representations, Defendants knew the "bolus" was over, (3) thus, at the time, there was no remaining potential for growth at the concentrated "ALS centers," (4) there was no growth potential for "newly diagnosed" patients with ALS, (5) the "General and Community Neurologist," did not provide opportunity for future growth, (6) Defendants already were aware that high, undisclosed discontinuation rates were occurring, undermining the commercial potential for the launch, and (7) those hidden discontinuations inflated the chance to grow the stated net patient subscribers.

E. Amylyx's Class Period Filings Did Not Comply With SEC Disclosure Requirements.

132. Amylyx's SEC filings identified above also failed to identify and disclose known trends, events, demands, commitments, and uncertainties that were then having and were reasonably likely to have a material effect on Amylyx's operating performance.

133. Item 7 of Form 10-K and Item 2 of Form 10-Q require SEC registrants to furnish the information called for under Item 303 of Regulation S-K [17 C.F.R. § 229.303], Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A"). Among other things, Item 303 of Regulation S-K required that Amylyx's Class Period Forms 10-K and

10-Q disclose known trends or uncertainties that had, or were reasonably likely to have, a material impact on its revenues or income from continuing operations.

134. In 1989, the SEC issued interpretative guidance associated with the requirements of Item 303 of Regulation S-K concerning the disclosure of material trends or uncertainties. As the interpretative guidance states:

Required disclosure is based on ***currently known trends, events, and uncertainties that are reasonably expected to have material effects***, such as: A reduction in the registrant's product prices; erosion in the registrant's market share; changes in insurance coverage; or the likely non-renewal of a material contract.

* * *

A disclosure duty exists where a trend, demand, commitment, event or uncertainty is both presently known to management and reasonably likely to have material effects on the registrant's financial condition or results of operation.

135. The 1989 Interpretive Release sets forth the following test to determine if disclosure under Item 303(a) is required:

Where a trend, demand, commitment, event or uncertainty is known, management must make two assessments:

- (1) Is the known trend, demand, commitment, event or uncertainty likely to come to fruition? If management determines that it is not reasonably likely to occur, no disclosure is required.
- (2) If management cannot make that determination, it must evaluate objectively the consequences of the known trend, demand, commitment, event or uncertainty, on the assumption that it will come to fruition. Disclosure is then required unless management determines that a material effect on the registrant's financial condition or results of operations is not reasonably likely to occur.

136. Additionally, the SEC published interpretive guidance, effective December 29, 2003, “regarding the disclosure commonly known as Management’s Discussion and Analysis of Financial Condition and Results of Operations, or MD&A, which is required by Item 303 of Regulation S-K, Items 303(b) and (c) of Regulation S-B, Item 5 of Form 20-F and Paragraph 11 of General Instruction B of Form 40-F.” In particular, the SEC advised that “companies must

identify and disclose known trends, events, demands, commitments and uncertainties that are reasonably likely to have a material effect on financial condition or operating performance,” citing the 1989 Interpretive Release as support and quoting, in footnote 6, the following text of the 1989 Interpretive Release:

MD&A mandates disclosure of specified forward-looking information, and specifies its own standards for disclosure – i.e., reasonably likely to have a material effect. The specific standard governs the circumstances in which Item 303 requires disclosure.

* * *

We believe that management’s most important responsibilities include communicating with investors in a clear and straightforward manner. MD&A is a critical component of that communication. The Commission has long sought through its rules, enforcement actions and interpretive processes to elicit MD&A that not only meets technical disclosure requirements but generally is informative and transparent.

137. Thus, the MD&A disclosures in Amylyx’s Forms 10-K and 10-Q it filed with the SEC during the Class Period were materially false and misleading because Defendants failed to disclose the known uncertainties associated with: (1) the declining level of new patient subscribers early on in the Relyvrio launch, (2) the high level of early discontinuations from those patients subscribed Relyvrio, (3) the lack of possible opportunities for growth after the initial patient bolus, (4) the accuracy of Amylyx’s reported subscriber numbers given the discontinuations inflated the amount of potential growth, and (5) the fact that Amylyx would not provide accurate, new patient additions or report on discontinuations, obscuring visibility into the objective success of the launch. As a result, these were events presenting known trends and uncertainties that were reasonably likely to—and, when they came to fruition during the Class Period, did—adversely affect Amylyx’s financial condition and results. The omission of this information violated the disclosure obligation imposed by Item 303.

F. The Truth Emerges.

138. On November 9, 2023, during pre-market hours, Amylyx issued a press release announcing its Q3 2023 financial results, including Q3 GAAP EPS of \$0.30, missing consensus estimates by \$0.12. That same day, on a conference call with investors and analysts to discuss these results (the “Q3 2023 Earnings Call”), Defendant Olinger revealed that, despite “a [purported] steady cadence of new prescriptions written in” Q3 for Relyvrio, patients were discontinuing treatment with Relyvrio after six months, stating, in relevant part:

[W]e saw a steady cadence of new prescriptions written in the third quarter . . . As we think about how our growth has evolved this year, ***the slowdown in net adds this quarter was primarily driven by increased discontinuations for a variety of reasons.***

* * *

60% of people taking RELYVRIO remain on therapy six months after initiation in the U.S. We believe some discontinuations are addressable[.]

(Emphasis added.)

139. Defendant Frates likewise confirmed on the Q3 2023 Earnings Call that “[o]ur results were impacted by a number of factors” including “what [Defendant Olinger] mentioned earlier”—*i.e.*, an increased rate of patients discontinuing treatment with Relyvrio and a slowdown in the net addition of new patients for Relyvrio.

140. Later that day, during intraday trading hours, *Investor’s Business Daily* published an article addressing the Company’s disappointing financial results, entitled “Amylyx Crashes 27% As New ALS Drug Faces A Barrage Of Troubles.” The *IBD* Article (as published during intraday trading hours³) stated, in relevant part:

³ During after-market hours, the *IBD* Article was later renamed “Amylyx Crashes 32% On A Quarterly Report That Doesn’t Bode Well For 2024,” the contents of which were slightly edited to, among other things, provide an update the Company’s stock price movement later in the day.

Amylyx . . . meaningfully missed Wall Street's expectations on Thursday amid struggles with its [ALS] drug. AMLX stock crashed in morning trades.

* * *

Amylyx noted patients are dropping off Relyvrio treatment after six months, Evercore ISI analyst Michael DiFiore said in a report. But Amylyx said the number of new patients starting treatment was "steady." DiFiore says his math suggests otherwise.

He also noted Amylyx blocked analysts from seeing Relyvrio prescription data this summer.

"Knowing that stock had underperformed in 2023 already, management could have communicated the discontinuations dynamic much earlier," he said. "Stock move today in a bad biotech tape and fund performance doesn't help investor confidence among folks that have held onto the stock."

In midday trades on today's stock market, AMLX stock plummeted 27.2% near 13.10.

AMMX Stock: Wide Sales, Earnings Misses

Overall, Relyvrio generated \$102.7 million in sales. Though sales grew almost 5% sequentially, they missed analysts' forecasts, which ranged from \$108.5 million to \$113.8 million, Mizuho Securities analyst Graig Suvannavejh said in a report.

* * *

Evercore's DiFiore says AMLX stock analysts' views for 2024 will "need to come down meaningfully." Analysts currently project \$591 million in U.S. sales of Relyvrio. But he says \$500 million is closer to what the Street should expect.

"I assume discontinuation rate at month six slows a bit — but not majorly," he said. "New adds improves a bit — but not majorly. Net price per patient stays flat."

141. Similarly, on the November 11, 2023 earnings call, investors understandably were puzzled by the Company's math not adding up. During the Q&A portion, one investor queried:

"If I just look at the fact pattern on how you implemented the data restriction on IMS and Symphony vendors this summer and how that coincided with this massive slowdown, it just really puzzles me because I feel like not only was the Street ready from communication on your end, but also I feel like you limited the channels to which Street could have been ready for today. How do you -- can you expand on

that? Because it looks like you may have had a sense for discontinuations really picking up around July timeframe.”

142. Defendant Cohen evaded responding to this timeline, instead saying “our intention at launch was always to have the limited distribution model” and that “we updated everyone in February that we thought we had identified one of the areas where there is some data coming out, and so we had addressed that.” “I think the most important thing here, though, is that we have huge long-term growth opportunities ahead of us.”

143. During that call, an analyst pressed that:

[I]f I model out on discontinuations, what I feel is it's not just the discontinuation. It's also the new starts might have dropped about 35%, 40% quarter-over-quarter from 2Q to 3Q. Is that right? Because I feel like you may have had about, I don't know, 750 discontinuations in 3Q. But if that's the case, you might be in for another about 650 to 700 discontinuations in 4Q, which makes it very hard to again put up a very meaningful net add number in 4Q unless your new add picks up very meaningfully versus where it was in 3Q. Am I on the right track there?

144. Defendant Cohen again did not respond to these accusations, but only stated that “[m]aybe we haven’t commented on any of those metrics, but maybe just to circle back. There are roughly 30,000 people living with ALS in the United States. We have 3,900 on therapy. So we certainly see an opportunity to continue to grow.”

145. Following these disclosures and the publication of the *IBD Article*, Amylyx’s stock price fell \$5.74 per share, or 31.89%, to close at \$12.26 per share on November 9, 2023.

146. As a result of Defendants’ wrongful acts and omissions, and the precipitous decline in the market value of the Company’s securities, Plaintiff and other Class members have suffered significant losses and damages.

G. Post-Class Period Developments.

147. On December 7, 2023—*i.e.*, less than a month after the truth regarding Relyvrio’s commercial prospects and prescription rates were revealed—Amylyx announced the departure of Defendant Olinger as the Company’s CCO, effective December 31, 2023. Although no explanation was given for her departure, as CCO, Defendant Olinger was primarily responsible for Relyvrio’s commercial development throughout the Class Period, and the timing of her departure appears to, at minimum, correlate with the negative revelations regarding Relyvrio’s commercial development as alleged herein.

148. On March 8, 2024, Amylyx issues a press release revealing that the Relyvrio Phase III Phoenix trial failed “to meet its primary endpoint of reaching statistical significance ($p=0.667$) as measured by change from baseline in the Revised Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFRS-R) total score at Week 48, nor was there statistical significance seen in secondary endpoints.” (Amylyx Press Release, March 8, 2024). In other words, Relyvrio “failed to slow the progression of the disease,” and “made no significant difference versus a placebo in terms of helping patients perform daily- living tasks such as walking and breathing.” (WSJ, “Wall Street Predicted a Blockbuster. Now the Drug May Be Withdrawn,” March 10, 2024).

149. Investors noted that the Phoenix trial did not just fail, it failed *badly*. “Importantly, the topline data fall into the worst-case scenario with $p=0.667$, suggesting there’s no trend observed from the data, including pre-specified subgroup analyses.” (Bank of America Global Research, “Amylyx Pharmaceuticals Complete PHOENIX failure,” March 8, 2024). As one report noted, “[w]e admit, we did expect at least a modest trend to efficacy to be detectable on the primary analysis in the absence of statistical significance, and, thus, the p-value, which implies essentially no separation (a <0.1 point/month difference on slope or a ~ 1 point difference on the ALSFRS-R

rate of change from the baseline vs. placebo based on our math, described below), is worse than we expected.” (Deutsche Bank Group, “Increasingly Hard for AMX0035 to Embody a PHOENIX,” March 8, 2024.)

150. As a result, Amylyx “voluntarily decided to pause promotion of the medication during this time” and would consider “voluntary withdrawal” from the market. (Amylyx Press Release, March 8, 2024). On a webcast that day, Defendant Cohen stated “[w]e plan to take swift action to understand the significance of this outcome with regulators and members of the ALS community.” (Refinitiv StreetEvents, “Amylyx Pharmaceuticals Inc To Provide Pharmaceuticals Phoenix Update,” March 8, 2024). When analysts asked for any information driving the Phoenix failure, Defendant Cohen would not respond, saying only that “I think as we’re going through this upcoming period, we’ll determine what the future of that analysis and everything is as well.”

151. “Investors didn’t take the news [of the Phoenix failure] well”—Amylyx stock “closed 82% lower” after this announcement. (WSJ, “Wall Street Predicted a Blockbuster. Now the Drug May Be Withdrawn,” March 10, 2024). “The decline signals that investors now think the drug is worth something close to zero, or perhaps less than that if one factors in continued expenses associated with it” and will be a “death blow” to Relyvrio. (*Id.*). This failure more broadly also “rais[ed] questions about the future of the drug and the company itself.” (*Id.*).

152. On April 4, 2024, speculation about Amylyx’s and Relyvrio’s future was partially answered when the Company confirmed it would “voluntarily withdraw” Relyvrio from the market. In a press release, the Company revealed it “has started a process with the [FDA] . . . to voluntarily discontinue the marketing authorizations for [Relyvrio] . . . and remove the product from the market in the U.S. and Canada based on topline results from the Phase 3 PHOENIX trial.”

(Amylyx Press Release, April 4, 2024). Thus, Relyvrio “will no longer be available for new patients as of today.” (*Id.*).

153. This forced a “restructuring to focus the Company’s financial resources on upcoming clinical milestones” for non-ALS indications, and stated that the “Company will reduce its workforce by approximately 70% and decrease external financial commitments outside of its priority areas.” (Amylyx Press Release, April 4, 2024).

154. In that release, the Company also stated “Amylyx will continue to evaluate and share learnings from PHOENIX to help inform future ALS research” and “[t]opline data from PHOENIX will be presented at the American Academy of Neurology (AAN) Annual Meeting in Denver and online, taking place April 13-18, 2024.” (Amylyx Press Release, April 4, 2024). “The presentation is scheduled to occur on April 16, 2024, during the Clinical Trials Plenary Session (9:15 a.m. – 11:30 a.m. MT) and will be made available on the “Publications and Presentations” section of the Company’s website following the conclusion of the presentation.” (*Id.*).

155. Yet to date, Amylyx has *not* provided any public information about why the Phoenix trial failed. Notably, contrary to its representations on April 4, 2024, Amylyx did *not* “present[]” any “topline [Phoenix] data at the American Academy of Neurology (AAN)” conference.

H. SCIENTER ALLEGATIONS

156. During the Class Period, Defendants had both the motive and opportunity to commit fraud. Moreover, Defendants had actual knowledge of the misleading nature of the statements they made, or acted in reckless disregard of the true information known to them at the time. In so doing, Defendants participated in a scheme to defraud and committed acts, practices,

and participated in a course of business that operated as a fraud or deceit on purchasers of the Company's securities during the Class Period.

157. ***Stock sales.*** Indeed, during the Class Period, while disseminating the materially false and misleading statements and omissions alleged herein that artificially inflated the market prices of Amylyx securities, Defendants Cohen and Klee each sold 105,968 shares of Amylyx common stock for total proceeds of over \$3.4 million, while Defendant Frates sold 100,158 shares of Amylyx common stock for total proceeds of over \$3 million. As FE2 related, FE2 added: "When you see mass amounts of stock being liquidated by the CEOs, the CFO, and the COO, and God knows who else because we didn't get information about [Defendant Olinger's] direct reports, but we knew they were also liquidating, we were like what do they know if they're liquidating? And why are they liquidating if they keep on telling us that the Phoenix trial is looking good?"

158. ***Defendants were aware of or recklessly disregarded the issues with the declining new subscribers and the high number of discontinuations that inflated the ramp for growth beyond the initial bolus of patients.*** As the former employees related, Defendants were tracking rates of new subscribers, and knew that the initial bolus of demand had severely tapered off within a few months of that launch initiated on October 24, 2022. Defendants also were aware of, and tracking, discontinuations in real time, and these dropouts were occurring mere weeks into the commercial launch. Despite this knowledge, Defendants, however, continued to represent that the drug presented opportunities for untapped growth. In addition, Defendants have vast experience with the nature of the ALS disease, and would know that there was no opportunity for growth within ALS centers after the bolus, newly diagnosed patients, or patients being treated by general neurologists. Surely if Amylyx's sales representatives knew of these realities, management did also.

159. *Defendants hid data on new subscribers and discontinuations from analysts throughout the launch.* Defendants stopped reporting new patient subscriber data to market research services, IQVIA and Symphony, in the summer of 2023. (Amylyx, Q3 2023 Earnings Call). And, despite discontinuations being a key metric necessary to evaluate true demand and potential for growth, and despite tracking these discontinuations in real time, Defendants repeatedly stated that they would not share that data, nor could they see any trends. Yet former employees reveal that in the initial bolus of demand, patients were discontinuing mere weeks after starting the treatment. Defendants took deliberate steps to hide this data from the market, notably by evading investor questions on the topic throughout the launch. In addition, Defendants adopted a “closed” pharmacy network, forbidding analysts from making their own informed judgments about the ongoing data. And, contrary to standard practice, Defendants refused to provide company-wide metrics on this data internally, obscuring its own employees from the true nature of the discontinuations, subscriber rates, and the ability for growth.

160. *While Defendants related internally that sales were not meeting targets, they represented to the market the launch was steady and thriving.* As former employees relate, Defendants’ statements to the market about steady, strong growth did not match the sentiments the sales teams received internally. Behind the closed doors of the Company, Defendants were panicked about the sales quotas not meeting their internal targets—panic that resulted in a toxic culture of unethical and desperate means to increase sales numbers at any cost.

161. *Post-class period developments support scienter.* That Amylyx later had to removed Relyvrio from the market supports an inference of scienter because it reinforces that Defendants knew throughout the commercial launch that the drug did not have long-term potential for growth. In addition, while Amylyx told the market that it would share the failed Phoenix trial

data, and present on it at an upcoming conference, to date Amylyx has provided no public information about why the trial failed and did not attend that conference. Moreover, Defendant Olinger’s departure so soon after the truth was revealed raises an inference of misconduct at the executive level with respect to the pharmaceutical launch and development of Relyvrio. Indeed, former employees reveal a culture of “blame game” at Amylyx to avoid the truth about why sales were not growing, contrary to market representations.

162. ***Defendants knew or acted with deliberate recklessness regarding the data on new subscribers and discontinuations given Relyvrio’s commercial success was essential to Amylyx’s core operations.*** As Relyvrio was Amylyx’s flagship product, and the only product approved for commercial use in the U.S., the outcome of this launch would make or break the Company. Indeed, when the Phoenix results revealed Relyvrio’s failure to achieve any statistical significance, Amylyx’s stock crashed 82%, forcing the Company to restructure and lay off 70% of its workforce. Given the dire stakes involved, it is not plausible that management would not be aware of the negative data about the drug’s near and long-term prospects.

I. **PLAINTIFF’S CLASS ACTION ALLEGATIONS**

163. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Amylyx securities during the Class Period (the “Class”); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

164. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Amylyx securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Amylyx or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

165. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

166. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

167. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Amylyx;
- whether the Individual Defendants caused Amylyx to issue false and misleading financial statements during the Class Period;

- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Amylyx securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

168. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

169. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Amylyx securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

- Plaintiff and members of the Class purchased, acquired and/or sold Amylyx securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

170. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

171. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

172. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

173. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

174. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout

the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Amylyx securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Amylyx securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

175. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Amylyx securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Amylyx's finances and business prospects.

176. By virtue of their positions at Amylyx, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

177. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers

and/or directors of Amylyx, the Individual Defendants had knowledge of the details of Amylyx's internal affairs.

178. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Amylyx. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Amylyx's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Amylyx securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Amylyx's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Amylyx securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

179. During the Class Period, Amylyx securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Amylyx securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true

value of Amylyx securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Amylyx securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

180. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

181. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

182. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

183. During the Class Period, the Individual Defendants participated in the operation and management of Amylyx, and conducted and participated, directly and indirectly, in the conduct of Amylyx's business affairs. Because of their senior positions, they knew the adverse non-public information about Amylyx's misstatement of income and expenses and false financial statements.

184. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Amylyx's financial condition and results of operations, and to correct promptly any public statements issued by Amylyx which had become materially false or misleading.

185. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Amylyx disseminated in the marketplace during the Class Period concerning Amylyx's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Amylyx to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Amylyx within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Amylyx securities.

186. Each of the Individual Defendants, therefore, acted as a controlling person of Amylyx. By reason of their senior management positions and/or being directors of Amylyx, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Amylyx to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Amylyx and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

187. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Amylyx.

V. PRAAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

- A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;
- B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

VI. DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: June 24, 2024

Respectfully submitted,

POMERANTZ LLP

/s/ Jeremy A. Lieberman

Jeremy A. Lieberman
J. Alexander Hood II
James M. LoPiano
600 Third Avenue, 20th Floor
New York, New York 10016
Telephone: (212) 661-1100
Facsimile: (917) 463-1044
jalieberman@pomlaw.com
ahood@pomlaw.com
jlo piano@pomlaw.com

Attorneys for Plaintiff